

REB Guidance and Information Document

Document Number	REB.INFO.404
Title	Ongoing Ethics Review
Effective Date	March 2022
Next Review	2027
Next Administrative Review	2024

1. Purpose

The purpose of this document is to provide guidance to researchers on their responsibilities in maintaining active research ethics clearance for their studies and the procedures for ongoing review.

2. Definitions

See the MSVU **REB Glossary of Terms (REB.INFO.001)**

3. Guidance/Information/Procedures

- 3.1. Article 2.8 of the [Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) (TCPS) stipulates that “Following initial REB review and approval, research ethics review shall continue throughout the life of the project in accordance with Article 6.14.”
- 3.2. Normally, continuing review will consist of at least the submission of a succinct annual status report to the UREB prior to the expiry date of the Certificate of Research Ethics Clearance. The UREB requires, as part of its approval process, annual status reports from researchers for ongoing research involving human participants. Annual reports and requests for renewals must be sent to the UREB (ethics@msvu.ca) 30 days **prior** to the expiry date of the certificate of ethics approval.
- 3.3. Research Ethics and the regulations that guide ethics review and clearance are constantly evolving in light of particular circumstances, and federal and provincial changes. Due to the evolutionary nature of researcher ethics, all research studies that involve human participants or their data shall be fully reviewed using a complete and up-to-date application after the fourth year of renewal (five years is normally the maximum length that an ethics file can be kept open and the active status of clearance is contingent upon receiving succinct annual report (REB.FORM.003) **prior** to the expiry date.
 - 3.3.1. Research Studies receive research ethics clearance in year one based on a complete application that has been reviewed and cleared by the UREB. This clearance may be renewed annually with the submission of a complete renewal request (annual report). Researchers may request a renewal up to 4 times (initial clearance plus 4 annual renewals)

- 3.3.2. Prior to the expiry in year **five**, researchers will submit a new application for research ethics clearance, revising where necessary to comply with the policies of the day and will submit a final report to close the previous file.
- 3.4. Faculty, staff, and students whose research studies have been reviewed and cleared by the UREB must provide the UREB with a succinct final report within 30 days of the expiry date of the certificate of ethics approval (REB.FORM.004). Continuing ethics approval and funding of the study is contingent upon timely receipt of a satisfactory annual report as indicated in Article 3.2 above.
- 3.4.1. Renewal requests received **after** the certificate of ethics clearance has expired, will not be processed. Researchers will be required to submit a new ethics application for review and approval by the UREB. In addition, researchers must suspend their current research with human participants or their data, until a new research ethics clearance is granted. No research with human participants or their data shall take place without a valid/active certificate of ethics clearance.
- 3.5. For all proposals vetted solely by a departmental research ethics board (DREB), a annual report for the department must be submitted either by the Chair or the person responsible for the DREB no later than June 30th of each year. Proposals that are not completed during the reporting year must be reported on the departmental report each and every year until complete.
- 3.5.1. The report must provide the following pertinent information:
- Student and/or class identification,
 - Type of project (class assignment, honours thesis) – Note – Honours students must also complete an annual or final report and submit this to the UREB,
 - Title or topic of study,
 - Supervisor,
 - Date of project submission, date of approval,
 - Status (e.g., complete versus incomplete),
 - Any outstanding issues.
- NOTE:** A spreadsheet prototype is available from the Research Ethics Office for optional use by departments/faculties.
- 3.7 Failure to comply with annual and final reporting procedures is in violation of the MSVU *Policy for Integrity in Research and Scholarship* and the UREB *Policy on Compliance* (REB.POL.003).
- 3.7.1 Researchers who have outstanding reports will not have research ethics applications that they are involved with vetted by the UREB or DREB until all reporting requirements have been satisfied.
- 3.7.2 Financial Services at Mount Saint Vincent University will be immediately notified of any funded researchers with outstanding reports as per the Memorandum of Understanding with the Tri-Council. Funds may be frozen at that time.

4. **Related Information and Documentation**

Researchers are reminded of the following requirements:	
Modifications	Any modifications to approved protocol must be reviewed <u>and</u> approved by the UREB prior to their implementation. Form: REB.FORM.002 Info: REB.SOP.404 Policy: REB.POL.003
Changes to Research Personnel	Any changes to approved persons with access to research data must be reported to the UREB immediately. Form: REB.FORM.002 Policy: REB.POL.003
Annual Renewal	Annual renewals are contingent upon an annual report submitted to the UREB prior to the expiry date as listed above. You may renew up to four times, at which point the file must be closed and a new application submitted for review. Form: REB.FORM.003 Info: REB.SOP.405 Policy: REB.POL.003
Final Report	A final report is due on or before the expiry date. Form: REB.FORM.004 Info: REB.SOP.406 Policy: REB.POL.003
Privacy Breach	Researchers must inform the UREB immediately and submit the Privacy Breach form. The breach will be investigated by the REB and the FOIPOP Officer. Form: REB.FORM.015
Unanticipated Research Event	Researchers must inform the UREB immediately and submit a report to the UREB within seven (7) working days of the event. Form: REB.FORM.008 Info: REB.SOP.404 Policy: REB.POL.003
Adverse Research Event	Researchers must inform the UREB immediately and submit a report to the UREB within two (2) working days of the event. Form: REB.FORM.007 Info: REB.SOP.404 Policy: REB.POL.003

5. **Notice to Researchers**

The information in this document is for information and guidance purposes only. Each research study poses unique properties and/or situations that may require additional or different guidance than what is presented in this document. The information in this document is meant to provide general situational advice and does not constitute research ethics compliance in absolute form. If you have any questions, please contact ethics@msvu.ca .

6. **Modification History**

INFO Number & Version	Key Changes	Effective Date
REB.INFO.404	The original SOP (REB.SOP.116) was converted to a new SOP - REB.SOP.404 in Fall 2021.The remaining portions of the original SOP document have been converted into a guidance document and is now renamed REB.INFO.404. The document is updated to reflect current policies and procedures. Minor revisions for clarity.	March 2022
REB.SOP.116	Version 2014 minor updates	June 2014
REB.SOP.116	Original SOP	February 2012

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